K 013446

510(k) SUMMARY

The Summary of Safety and Effectiveness on the GluSite reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

Applicant	Don Blacklock GluStitch, Inc. DEC 2 0 2001 7188 Progress Way, #307 Delta, BC., V4G 1M6
Telephone	(800) 667-2130
Facsimile	(877) 450-4000
Date	October 15, 2001
Name	GluSite
Classification	Dental Cement, 21 CFR 872.3275
Predicate:	CLOSURE Medical Corporation's Octyldent®, K980159 – market clearance date, April 9, 1998
Description	GluSite (2-octyl cynoacrylate) is a clear colorless, free-flowing liquid monomer packaged in a glass multiple-use vials. Upon contact with weak bases, GluSite polymerizes to form a strong adhesive bond. Depending on the availability of moisture, this could take up to one minute.
Intended Use	GluSite is indicated for use as dental cement for bonding dental materials such as crowns, caps, and pins, or temporarily attaching a fiber to the surface of the tooth in a procedure to treat periodontal disease.
Contraindication:	• GluSite is contraindicated for use in patients with hypersensitivity to the adhesive. • GluSite must not come in contact with the conjunctival sac since conglutination may occur.
Caution:	• Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
Technological Characteristics	The intended use of the GluStitch, Inc.'s GluSite and CLOSURE Medical Corporation's Octyldent® are equivalent. The chemical composition, octyl cyanoacrylate are equivalent, and test results demonstrates that the two devices are equivalent in performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2001

Mr. Donald Blacklock
President
GluStitch, Incorporated
#307 7188 Process Way
Delta, British Columbia,
CANADA

Re: K013446
Trade/Device Name: GluSite
Regulation Number: 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: October 15, 2001
Received: October 15, 2001

Dear Mr. Blacklock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013446

Device Name: GluSite

Indications For Use:

GluSite is indicated for use as dental cement for bonding dental materials such as crowns, caps, and pins, or temporarily attaching a fiber to the surface of the tooth in a procedure to treat periodontal disease.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013446